



Effectiveness of Treadmill Training in Children with Motor Impairments

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Introduction

This document contains a brief overview of information regarding the effectiveness of treadmill training with and without body weight support in children with motor impairments such as cerebral palsy (CP), Down syndrome (DS), spina bifida (SB), spinal cord injury (SCI) as well as other motor impairments.

How was the literature review completed?

An electronic search was performed in May 2012 of the following databases: EBM Reviews, CINAHL, MEDLINE, and PEDRO. Keywords used in the search included for example: 'treadmill', 'cerebral palsy', 'spina bifida', 'spinal cord injury' and 'down syndrome.' (For a detailed look at the search strategy used, please contact the author.) Systematic reviews were sought out to summarize research findings. The American Academy for Cerebral Palsy and Developmental Medicine (AAPDM) Levels of Evidence¹ were assigned to relevant studies with scores reported throughout the document (see Table 1). Publications with the highest levels of evidence or novel approaches published since the most recent systematic reviews were also included in this summary. Included manuscripts were rated using two quality rating scales: the AMSTAR² scale was used to rate quality of included systematic reviews and the AAPDM Conduct Rating Scale for Group Design¹ was used to rate quality of included original studies. Finally, the International Classification for Functioning, Disability and Health (ICF) was used to describe study outcomes.³

What is Treadmill Training?

Treadmill training (TT) involves exercising on a treadmill with or without partial body weight support. TT is congruent with contemporary models of motor control and motor learning that recommend a task-specific approach with emphasis on repetition and practice.⁴ **Partial body weight support treadmill training (PBWSTT)** involves the use of a body-weight support harness during the treatment. More specifically, this partial unweighting allows the child to practice walking at a faster, more typical pace without the exertion associated with overground walking.⁵ The support harness also allows therapists to use their hands to manually assist the child in walking. **Robotic TT** has been developed as an alternative to PBWSTT. This method utilizes a motorized gait orthosis to support the child over the treadmill and passively guide the movement.⁶ TT using an electromechanical **gait trainer** such as the Gait Trainer GT has also been proposed as an alternative to PBWSTT and robotic TT.⁷ This type of gait trainer involves positioning individuals in a harness with two footplates whose movement simulates gait. The use of this type of gait trainer is meant to require less therapist assistance than PBWSTT as well as reduced positioning time for robotic TT. Finally, **lower body positive pressure supported TT (LBPPSTT)** has recently emerged as an alternative method of supporting a child's weight over a treadmill. In this system, the treadmill is enclosed in an inflatable bag and air pressure is used to support the child over the treadmill.⁸

Is Treadmill Training Effective?

Two systematic reviews and 21 original studies representing the highest available levels of evidence were included in this summary.^{6-9, 15-33} These include a 2010 systematic review of systematic reviews

(from now on referred to as “umbrella review”)⁹ on various types of TT used with children with motor impairments summarizing the results of five systematic reviews published between 2006 and 2009¹⁰⁻¹⁴ as well as a 2011 Cochrane systematic review¹⁵ on PBWSTT in zero to six year old children at risk for neuromotor delays. Table 1 summarizes these studies as well as the higher level publications included in the overview and Cochrane review.

No negative outcomes were reported in any of the reviews or studies using non-robotic TT; however, many individual studies did not report the presence or absence of adverse outcomes in their research. One large level IV study utilizing robotic TT did mention that 43% of participants did report an adverse event (muscle pain, joint pain, skin erythema, open skin lesions and tendinopathy) but that these were clinically insignificant in that they did not interfere with treatment.⁶

In an effort to report all study outcomes in a similar manner, and since many studies had sample sizes that were too small to allow for statistical analysis or to detect significant differences, outcomes in this summary are reported as positive if there was a trend toward better outcomes or if more than half of the sample achieved positive gains. Results that were statistically significant are represented in bold. Results that were inconclusive or showed no changes are combined in one column (see Tables 2-5).

Cerebral Palsy

A high number of studies regarding the use of different varieties of TT have been conducted in children with CP (see Table 2).^{6-8,16-20} The levels of evidence of these studies continue to mostly be at a level of IV or V, however two level II randomized controlled trials (RCTs)^{16,17} and one level III study¹⁸ have examined the use of PBWSTT in children with CP. Overall results from these high level studies as well as those synthesized in the overview and Cochrane review are conflicting in both the Body Structure and Function (BS&F) and Activities and Participation (A&P) dimensions of the ICF. In particular, improvements in gait, aerobic capacity and functional mobility show the most mixed results between studies. In addition, the two recently published level II RCTs reported no advantage of PBWSTT over overground walking or strength training in improving outcomes;^{16,17} both studies may have been underpowered to detect significant differences between groups due to the smaller than expected sample size. However, these results are in line with the findings for the 0-6 year old population included in the Cochrane review as well as the umbrella review.^{9,15}

One level II RCT examined the use of TT with neuromuscular electrical stimulation (NMES) in children with CP and found improvements in dimensions D and E of the Gross Motor Function Measure (GMFM).¹⁹ In addition Kurz et al. examined the use of a novel mode of TT, LBPPSTT, in children with CP (level IV) and found that this intervention might have a positive impact on various parameters of BS&F including gait, lower extremity strength and balance.⁸ Two level IV studies also examined the use of robotic PWBSTT and both determined that robotic PBWSTT might be effective in improving GMFM dimensions D and E.^{6,20} Lastly, Smania et al completed a level II RCT evaluating the use of a novel gait trainer and determined that individuals who participated in the gait trainer program had significantly improved outcomes in their 6-minute walk tests than their counterparts who completed conventional physiotherapy sessions; this difference was maintained one month post-intervention.⁷

Down Syndrome

A number of high level studies support the use of TT in children with DS (see Table 3).²¹⁻²⁷ These results are corroborated by the results of the TT umbrella review and recent Cochrane review.^{9,15} Multiple studies (level II) albeit from only two samples, suggest a number of statistically significant results in gait parameters as well as age of onset of walking when using TT only in infants with DS²¹⁻²⁶ and with better results when not wearing supra-malleolar orthotics.²⁷ However, a significant lack of evidence exists regarding the effects of TT on A&P in these children, an important gap in currently available research.

Spina Bifida

Promising results have been published very recently in two studies (level II²⁸ and level V²⁹) evaluating the use of TT in children with SB (see Table 4). The level II study reported statistically significant short and longer-term effects in BS&F outcomes.²⁸ The level V study's results suggest that the toddler achieved functional walking on the earlier end of the spectrum than what is reported for children with his or her level of impairment in addition to other improvements in BS&F outcomes.²⁹

Spinal Cord Injury

Research regarding the effectiveness of different types of TT in children with SCI is beginning to emerge (four recent level IV & V studies) and results of the original studies which are also corroborated in the TT umbrella review⁹ suggest positive results may be possible for A&P outcomes albeit receiving mixed results for BS&F outcomes (see Table 5).³⁰⁻³³

What parameters and protocols should be used?

Cerebral Palsy

In terms of parameters of intervention, studies have been highly variable in their use of different types of TT, speed, BWS, time per session, frequency, and duration.^{6-8,16-20} It is therefore difficult to suggest which parameters might be responsible for creating positive outcomes. Level II & III studies used various modes of TT for four to 12 weeks, two to five times per week, one to two times per day with BWS starting at approx 40 % and reduced to as close to 0%, and highly variable speeds.^{6,7,16-20}

Down Syndrome

Intervention parameters in this population have been quite consistent and suggest that intervention using a speed of approximately 20 cm/s (0.72km/hr or 0.45 miles/hr) for six to nine minutes, five to seven days per week until the achievement of independent walking can have important effects on BS&F.²¹⁻²⁷

Spina Bifida

Research surrounding the use of TT in this population is very limited, however, the level II study included a TT program consisting of 21-32 minute sessions, two times per week for 12 weeks.²⁸ The level V study involved using TT with progressive use of a walker to achieve functional walking in a toddler with an L4-L5 level lesion.²⁹ TT consisted of the child being held over the treadmill by a parent a minimum of five times per week for a total of 25 minutes per week for 18 weeks.

Spinal Cord Injury

All studies pertaining to SCI utilized one or more modes of PBWSTT with a BWS percentage starting around 40-80% and decreasing as the intervention period progressed. Intervention was three or more times per week for greater than eight weeks in duration.³⁰⁻³³















Can treadmill training be recommended for children with motor impairments?

Based on outcomes from the highest available level of evidence publications, grades of recommendation can be offered for each diagnostic group and form of TT; grades are defined in Appendix IV³⁴ and TT recommendations are summarized in Figure 1.

Figure 1. Grades of Recommendation for Treadmill Training in Children with Motor Impairments

Diagnosis	ICF Dimension	Outcome	TT Only	PBWSTT	PPLBSTT	Robotic PBWSTT	Gait Trainer	Mixed TT
Cerebral Palsy	Body Structure & Function	Gait	With NMES Proven Ineffective	 Conflicting	 Insufficient	 Insufficient	 Conflicting	
		Aerobic Capacity		 Conflicting			 Proven Effective	
		Strength		 Proven Ineffective	 Insufficient			
		Balance			 Insufficient			
		Neurological Status		 Proven Ineffective				
	Activity & Participation	Gross Motor Skills	With NMES Proven Effective	 Proven Ineffective		 Insufficient		
		Functional Mobility			 Conflicting		 Conflicting	
Down Syndrome	Body Structure & Function	Gait Parameters	 Proven Effective					
		Age of Onset of Walking	 Proven Effective					

NMES: Neuromuscular Electrical Stimulation.

Diagnosis	ICF Dimension	Outcome	TT Only	PBWSTT	PPLBSTT	Robotic PBWSTT	Gait Trainer	Mixed TT
Spina Bifida	Body Structure & Function	Body Composition	 Insufficient					
		Aerobic Capacity	 Proven Effective					
		Muscle Strength	 Insufficient					
		Age of Onset of Walking	 Insufficient					
	Activity & Participation	Functional Mobility	 Insufficient					
		Caregiver Support	 Insufficient					
		Quality of Life	 Insufficient					
Spinal Cord Injury	Body Structure & Function	Muscle activity	 Insufficient					
		Gait	 Insufficient					
		Neurological Status	 Insufficient					
		Range of Motion	 Insufficient					
		Aerobic Capacity	 Insufficient					
		Tone	 Insufficient					
	Activity & Participation	Functional Mobility	 Insufficient					

In summary, no adverse events have been reported when using TT in pediatric populations. With the exception of children with Down syndrome, due to the lower levels of evidence and conflicting results in the TT literature, it is recommended that clinicians choosing to use TT measure meaningful client and family outcomes to ensure that the intervention is having the desired effect.

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Table 1: Assigned Levels of Evidence and Quality Scores for Studies

Participant Diagnosis	Intervention	Reference	Study Design	AAPDM Level of Evidence ¹	Quality Rating Score		Unique Sample	Participant Age
					AMSTAR ²	AACPDM ¹		
Cerebral Palsy	TT with NMES	Chan ¹⁹⁺	RCT	II	NA	5/7 - M	Y	N=12 Preschool & School Age Di & Hemiplegia
	PBWSTT	Dodd ¹⁸⁺	Clinical Controlled Trial	III	NA	5/7 - M	Y	N=14 School Age Di & Quadriplegia GMFCS III & IV
		Johnston ¹⁶	RCT	II	NA	4/7 - M	Y	N=26 School Age Di, Tri, Quadriplegia GMFCS II-IV
		Willoughby ¹⁷	RCT	II	NA	3/7 - W	Y	N=26 School Age GMFCS III & IV
	LBPPSTT	Kurz ⁸	Case Series	IV	NA	NA	Y	N=9 School Age Di & Hemiplegia GMFCS II-IV
	Robotic PBWSTT	Borggraefe ²⁰	Case Series	IV	NA	NA	Y	N=20 School Age Bilateral Spastic GMFCS I-IV
	Gait Trainer	Smania ⁷	RCT	II	NA	6/7 - S	Y	N=20 School Age Di & Triplegia GMFCS II-IV
Down Syndrome	TT only	Ulrich ^{21*+}	RCT	II	NA	4/7 - M	Y	N=30 Infants
		Angulo-Barroso ²²⁺						
		Angulo-Barroso ^{23*+}						
		Ulrich ^{24*+}	RCT	II	NA	6/7 - H	Same as Ulrich 2008	N=36 Infants
		Wu ^{25*+}						
	Wu ^{26*}							
	TT with SMOs	Looper ^{27*}	RCT	II	NA	4/7 - M	Y	N=17 Infants

Participant Diagnosis	Intervention	Reference	Study Design	AAPDM Level of Evidence ¹	Quality Rating Score		Unique Sample	Participant Age
					AMSTAR ²	AACPDM ¹		
Spina Bifida	TT only	deGroot ²⁸	RCT	II	NA	4/7 - M	Y	N=32 School Age
	Mixed TT	Moerchen ²⁹	Case Report	V	NA	NA	Y	N=1 Toddler L4-5
Spinal Cord Injury	PBWSTT	Dietz ³⁰⁺	Case Series	IV	NA	NA	Same as Dietz ^{1998A}	N=14 of which 2 School Age C5 & C6 ASIA C & D
		Dietz ³¹⁺						
	Mixed TT	Behrman & Harkema ³²⁺	Case Series	IV	NA	NA	Y	N=4 of which 2 Young Adults T5 & 6 ASIA A & C
		Behrman ³³⁺	Case Report	V	NA	NA	Y	N=1 Preschool Age C6; ASIA C
Mixed	PBWSTT	Valentin-Gudiol ¹⁵	SR	II	10/11 - H	NA	NA	Children at risk for motor delay Infant, Toddler, Preschool
	Mixed TT	Zwicker & Mayson ⁹	SR	II	8/11 - H	NA	NA	Children with Motor Impairments All Ages
	Robotic TT	Borggraefe ⁶	Case Series	IV	NA	NA	Y	N=89 of which 58 had CP School Age

*Included in Cochrane Review; ⁺Included in Overview; AAPDM: American Academy for Cerebral Palsy and Developmental Medicine; AMSTAR Rating: H=High; M=Moderate; L=Low; AAPDM Rating: S=Strong; M=Moderate; W=Weak for AAPDM levels of evidence I through III only; RCT: Randomized Controlled Trial.

Table 2. Cerebral Palsy: Outcomes by Level of Evidence and ICF Dimension

	Positive Outcomes					No Change or Inconclusive				
	II	III	IV	V	II	III	IV	V		
TT + NMES										
BODY STRUCTURE AND FUNCTION										
Ankle moment quotient						Chan ¹⁹				
Ankle power quotient						Chan ¹⁹				
ACTIVITY AND PARTICIPATION										
GMFM D	Chan ¹⁹									
GMFM E	Chan ¹⁹									
PBWSTT										
BODY STRUCTURE AND FUNCTION										
Spasticity						Johnston ^{16o}				
Strength						Johnston ^{16o}				
Motor Control						Johnston ^{16o}				
Velocity – undefined	Johnston ^{16o+}									
Cadence	Johnston ^{16o}									
Stride/step length						Johnston ^{16o}				
10-minute walk test			Dodd			Willoughby ^{17o}				
ACTIVITY AND PARTICIPATION										
GMFM Total						Johnston ^{16o}				
10 –meter walk test			Dodd ¹⁸			Willoughby ^{17o}				
School Function Assessment – Travel Section	Willoughby ^{17o}									
PODCI – global	Johnston ^{16o+}									
PODCI – transfers and mobility						Johnston ^{16o}				
PPLBSTT										
BODY STRUCTURE AND FUNCTION										
Walking velocity				Kurz ⁸						
Cadence									Kurz ⁸	
Stride/step length				Kurz ⁸						
Stride time									Kurz ⁸	
Double support				Kurz ⁸						
Step width									Kurz ⁸	
Lower extremity strength				Kurz ⁸						
BESTest				Kurz ⁸						
Robotic PBWSTT										
BODY STRUCTURE AND FUNCTION										
Velocity				Borggraefe ⁶						
6 minute walk test				Borggraefe ^{6*}						
ACTIVITY AND PARTICIPATION										
GMFM D				Borggraefe ²⁰						
				Borggraefe ^{6*}						
GMFM E				Borggraefe ²⁰						
				Borggraefe ^{6*}						
Gait Trainer										
BODY STRUCTURE AND FUNCTION										
Joint kinematics						Smania ⁷				
Velocity	Smania ^{7^}									
Cadence`						Smania ⁷				
Step length	Smania ^{7^}									
6 minute walk test	Smania ^{7^}									
ACTIVITY AND PARTICIPATION										
10-meter walk test	Smania ^{7^}									
WeeFIM						Smania ⁷				

Statistically significant results indicated in **bold**; BESTest: Balance Evaluation System Test; GMFM; Gross Motor Function Measure; NMES: Neuromuscular Electrical Stimulation; TT: Treadmill Training; PBWS: Partial Body Weight Support; PODCI: Pediatrics Outcomes Data Collection Instrument; PPLBS: Positive Pressure Lower Body Support; WeeFIM: Functional Independence Measure for Children.

° No difference between groups immediately post-intervention (Johnston: PBWSTT vs. strength training; Willoughby: PBWSTT vs. overground walking)

+ Maintained at 1 month post-intervention in PBWSTT group only.

* Maintained at 6 months post-intervention (no comparison group) although some participants continued with robotic PBWSTT.

^ Maintained at 1 month post-intervention.

Table 3. Down Syndrome: Outcomes by Level of Evidence and ICF Dimension

	Positive Outcomes ^a				No Change or Inconclusive			
	II	III	IV	V	II	III	IV	V
TT Only								
BODY STRUCTURE AND FUNCTION								
Velocity - undefined	A-B ²³							
Pre-obstacle velocity	Wu ²⁵							
Cadence	A-B ²³							
Pre-obstacle cadence	Wu ²⁵							
Stride/step length	A-B ²³							
Pre-obstacle step length	Wu ²⁵							
% Double support	A-B ²³							
Joint kinematics	Wu ²⁶							
Foot rotation	A-B ²³							
Asymmetry	A-B ²³							
Step width	A-B ²³							
Pre-obstacle step width	Wu ²⁵							
Dynamic base	A-B ²³							
1st principal component of gait	A-B ²³							
Trunk & leg low activity duration	A-B ²²							
Trunk & leg high activity duration	A-B ²²							
Actiwatch	A-B ²²							
Treadmill steps	Ulrich ²⁴							
BSID-II 8 items								Ulrich ²⁴
1st principal component of 8 BSID-II	Ulrich ²⁴							
Onset of « up to stand »	Ulrich ²¹							
Onset of « walk with help »	Ulrich ²¹							
Onset of « walk 3 steps independently »	Ulrich ²¹							
Strategy of obstacle negotiation	Wu ²⁵							
ACTIVITY AND PARTICIPATION								
GMFM	Looper & Wu ^{26°}							

Statistically significant results indicated in **bold**; A-B: Angulo-Barroso (author); BSID: Bayley Scales of Infant Development, 2nd Edition; GMFM: Gross Motor Function Measure; TT: Treadmill Training.

° Significant difference between groups with supra-malleolar orthoses (SMO) and TT group demonstrating lower GMFM scores than control.

Table 4. Level of Evidence for ICF Outcomes in Spina Bifida

	Positive Outcomes ^a				No Change or Inconclusive			
	II	III	IV	V	II	III	IV	V
TT Only								
BODY STRUCTURE AND FUNCTION								
Weight					de Groot ²⁸			
Body mass index					de Groot ²⁸			
Sum of skinfolds					de Groot ²⁸			
Strength: handgrip and quads	de Groot ²⁸							
6 minute walk test	de Groot^{28*}							
Energy cost					de Groot ²⁸			
Energy consumption	de Groot^{28*}							
VO2	de Groot²⁸							
Maximum walking speed	de Groot^{28*}							
ACTIVITY AND PARTICIPATION								
Peds QL	de Groot ²⁸							
Mixed TT								
BODY STRUCTURE AND FUNCTION								
Age at onset of independent walking				Moerchen ²⁹				
ACTIVITY AND PARTICIPATION								
Functional mobility scales				Moerchen ²⁹				
PEDI – mobility				Moerchen ²⁹				
PEDI – caregiver support				Moerchen ²⁹				

Statistically significant results indicated in **bold**; Peds QL: Pediatric Quality of Life Questionnaire; PEDI: Pediatric Evaluation of Disability Inventory; TT: Treadmill Training; VO2: Maximal Oxygen Uptake.

*Maintained at 3 months post-intervention.

Table 5. Spinal Cord Injury: Number of Reported Outcomes by Level of Evidence and ICF Dimension

	Positive Outcomes ^a				No Change or Inconclusive			
	II	III	IV	V	II	III	IV	V
PBWSTT								
BODY STRUCTURE AND FUNCTION								
Gastrocnemius EMG activity in stance			Dietz ^{30,31}					
Tibialis anterior EMG activity in swing			Dietz ^{30,31}					
Somatosensory & motor EPs							Dietz ^{30,31}	
MIXED TT								
BODY STRUCTURE AND FUNCTION								
Free velocity				Behrman ³³			Behrman ³²	
Fast velocity				Behrman ³³			Behrman ³²	
Range of motion of hip, knee & ankle								Behrman ³³
ASIA level						Behrman ³²		Behrman ³³
Modified Ashworth scale								Behrman ³³
Clonus								Behrman ³³
Babinski								Behrman ³³
Lower extremity motor score								Behrman ^{32,33}
2 minute walk test						Behrman ³²		
Step watch				Behrman ³³				
ACTIVITY AND PARTICIPATION								
FIM - locomotion						Behrman ³²		
WeeFIM - self-care								Behrman ³³
WISCI II - standing & walking				Behrman ³³				

Statistically significant results indicated in **bold**; ASIA: American Spinal Injury Association; EMG: Electromyography; EPs: Evoked Potentials; FIM: Functional Independence Measure; PBWS: Partial-Body Weight Support; TT: Treadmill Training; WeeFIM: Functional Independence Measure for Children; WISCI II: Walking Index for Spinal Cord Injury, 2nd ed.

Appendix I: AACPDM - Levels of Evidence for Group Intervention Studies (December 2008)¹

Level	Group Intervention Studies
I	Systematic review of randomized controlled trials (RCTs) Large RCT (with narrow confidence intervals) (n>100)
II	Smaller RCTs (with wider confidence intervals) (n<100) Systematic reviews of cohort studies “Outcomes research” (very large ecologic studies)
III	Cohort studies (must have concurrent control group) Systematic reviews of case control studies
IV	Case series Cohort study without concurrent control group (e.g. with historical control group) Case-control study
V	Expert opinion Case study or report Bench research Expert opinion based on theory or physiologic research Common sense/anecdotes

AACPDM: American Academy for Cerebral Palsy and Developmental Medicine.

Appendix II: AMSTAR Conduct Rating for Systematic Reviews²

Systematic Review Being Appraised (list author name):

Valentin-Gudiol¹⁵Zwicker⁹**1. Was an 'a priori' design provided?**

The research question and inclusion criteria should be established before the conduct of the review.

 Yes No Can't answer Not applicable Yes No Can't answer Not applicable Yes No Can't answer Not applicable Yes No Can't answer Not applicable Yes No Can't answer Not applicable Yes No Can't answer Not applicable**3. Was a comprehensive literature search performed?**

At least two electronic sources should be searched. The report must include years and databases used (e.g. Central, EMBASE, and MEDLINE). Key words and/or MESH terms must be stated and where feasible the search strategy should be provided. All searches should be supplemented by consulting current contents, reviews, textbooks, specialized registers, or experts in the particular field of study, and by reviewing the references in the studies found.

 Yes No Can't answer Not applicable Yes No Can't answer Not applicable**4. Was the status of publication (i.e. grey literature) used as an inclusion criterion?**

The authors should state that they searched for reports regardless of their publication type. The authors should state whether or not they excluded any reports (from the systematic review), based on their publication status, language etc.

 Yes No Can't answer Not applicable Yes No Can't answer Not applicable**5. Was a list of studies (included and excluded) provided?**

A list of included and excluded studies should be provided.

6. Were the characteristics of the included studies provided?

In an aggregated form such as a table, data from the original studies should be provided on the participants, interventions and outcomes. The ranges of characteristics in all the studies analyzed e.g. age, race, sex, relevant socioeconomic data, disease status, duration, severity, or other diseases should be reported.

- | | |
|---|---|
| <input checked="" type="checkbox"/> Yes | <input checked="" type="checkbox"/> Yes |
| <input type="checkbox"/> No | <input type="checkbox"/> No |
| <input type="checkbox"/> Can't answer | <input type="checkbox"/> Can't answer |
| <input type="checkbox"/> Not applicable | <input type="checkbox"/> Not applicable |
| <input checked="" type="checkbox"/> Yes | <input checked="" type="checkbox"/> Yes |
| <input type="checkbox"/> No | <input type="checkbox"/> No |
| <input type="checkbox"/> Can't answer | <input type="checkbox"/> Can't answer |
| <input type="checkbox"/> Not applicable | <input type="checkbox"/> Not applicable |
| <input checked="" type="checkbox"/> Yes | <input checked="" type="checkbox"/> Yes |
| <input type="checkbox"/> No | <input type="checkbox"/> No |
| <input type="checkbox"/> Can't answer | <input type="checkbox"/> Can't answer |
| <input type="checkbox"/> Not applicable | <input type="checkbox"/> Not applicable |

7. Was the scientific quality of the included studies assessed and documented?

'A priori' methods of assessment should be provided (e.g., for effectiveness studies if the author(s) chose to include only randomized, double-blind, placebo controlled studies, or allocation concealment as inclusion criteria); for other types of studies alternative items will be relevant.

8. Was the scientific quality of the included studies used appropriately in formulating conclusions?

The results of the methodological rigor and scientific quality should be considered in the analysis and the conclusions of the review, and explicitly stated in formulating recommendations.

9. Were the methods used to combine the findings of studies appropriate?

For the pooled results, a test should be done to ensure the studies were combinable, to assess their homogeneity (i.e. Chi-squared test for homogeneity, I²). If heterogeneity exists a random effects model should be used and/or the clinical appropriateness of combining should be taken into consideration (i.e. is it sensible to combine?).

10. Was the likelihood of publication bias assessed?

An assessment of publication bias should include a combination of graphical aids (e.g., funnel plot, other available tests) and/or statistical tests (e.g., Egger regression test).

11. Was the conflict of interest stated?

Potential sources of support should be clearly acknowledged in both the systematic review and the included studies.

- | | |
|---|--|
| <input checked="" type="checkbox"/> Yes | <input type="checkbox"/> Yes |
| <input type="checkbox"/> No | <input type="checkbox"/> No |
| <input type="checkbox"/> Can't answer | <input type="checkbox"/> Can't answer |
| <input type="checkbox"/> Not applicable | <input checked="" type="checkbox"/> Not applicable |
| <input type="checkbox"/> Yes | <input type="checkbox"/> Yes |
| <input checked="" type="checkbox"/> No | <input checked="" type="checkbox"/> No |
| <input type="checkbox"/> Can't answer | <input type="checkbox"/> Can't answer |
| <input type="checkbox"/> Not applicable | <input type="checkbox"/> Not applicable |
| <input checked="" type="checkbox"/> Yes | <input checked="" type="checkbox"/> Yes |
| <input type="checkbox"/> No | <input type="checkbox"/> No |
| <input type="checkbox"/> Can't answer | <input type="checkbox"/> Can't answer |
| <input type="checkbox"/> Not applicable | <input type="checkbox"/> Not applicable |
| <input checked="" type="checkbox"/> Yes | <input checked="" type="checkbox"/> Yes |
| <input type="checkbox"/> No | <input type="checkbox"/> No |
| <input type="checkbox"/> Can't answer | <input type="checkbox"/> Can't answer |
| <input type="checkbox"/> Not applicable | <input type="checkbox"/> Not applicable |
| 10 | 8 |

Total Score (1 for each 'yes' rating):

Quality Rating³⁵

High Quality:

8 to 11

Moderate Quality:

4 to 7

Low Quality:

0 to 3



Appendix III: AACPDM Conduct Questions for Original Group Design with Levels of Evidence I-III¹

	Chan ¹⁹	Johnston ¹⁶	Willoughby ¹⁷	Dodd ¹⁸	Smania ⁷	Ulrich ²¹	Ulrich ²⁴	Looper & Wu ²⁷	de Groot ²⁸
1. Were inclusion and exclusion criteria of the study population well described and followed?	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No
2. Was the intervention well described and was there adherence to the intervention assignment? (for 2-group designs, was the control exposure also well described?) Both parts of the question need to be met to score 'yes'.	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
3. Were the measures used clearly described, valid and reliable for measuring the outcomes of interest?	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
4. Was the outcome assessor unaware of the intervention status of the participants (i.e., were the assessors masked)?	No	No	No	No	Yes	No	No	No	No
5. Did the authors conduct and report appropriate statistical evaluation including power calculations? Both parts of the question need to be met to score 'yes'.	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
6. Were dropout/loss to follow-up reported and less than 20%? For 2-group designs, was dropout balanced?	Yes	No	No	Yes	Yes	Yes	Yes	No	Yes
7. Considering the potential within the study design, were appropriate methods for controlling confounding variables and limiting potential biases used?	No	No	No	No	No	Yes	Yes	No	No
Total Score	5	4	3	5	6	4	6	4	4

AACPDM: American Academy for Cerebral Palsy and Developmental Medicine.

Quality Rating for AACPDM levels of evidence I through III.¹

Strong (well conducted): 6 to 7
 Moderate (fairly conducted): 4 to 5
 Weak (poorly conducted): 0 to 3

Appendix IV: Traffic Lighting Classification Scale³³

Colour Code	Criteria	State of the Evidence
	Group design Level I or II evidence of good* quality demonstrating negative outcomes (e.g. absence of change compared to no treatment)	<p style="text-align: center;">Proven Ineffective</p>
	<ul style="list-style-type: none"> • Group design Level I or II evidence of poor[∞] quality regardless of outcome • Group design Level III-V evidence of any quality regardless of outcome • Single study research design Level I-V of any quality regardless of outcome • Inconclusive results 	<p style="text-align: center;">Insufficient Evidence</p>
	No evidence about the intervention's effectiveness	<p style="text-align: center;">No Evidence</p>
	Group design of either Level I or II evidence, where both studies of the same level of evidence show conflicting results	<p style="text-align: center;">Conflicting Evidence</p>
	Group design Level I or II evidence of good* quality, demonstrating statistically significant positive outcomes	<p style="text-align: center;">Proven Effective</p>

*Moderate or Strong quality (Group Design AACPDM Conduct Rating Scale¹ score of 4-7 or AMSTAR² score of 4-11)

[∞]Weak quality (Group Design AACPDM Conduct Rating Scale¹ or AMSTAR² score of 1-3)